SEP 2 8 2001

SECTION E - 510(k) SUMMARY K012428

Submitter's Name and Address:

Medtronic Physio-Control Corp.
11811 Willows Road Northeast
P.O. Box 97006
Redmond, WA 98073

Contact Person:

Sherri L. Pocock, Esq.
(425) 867-4332

Date Summary Prepared:

August 29, 2001

Device:

Medtronic Physio-Control LIFEPAK® 500 Automated External Defibrillator (biphasic and monophasic versions)

Classification:

Low-Energy DC – Defibrillator (360 Joules maximum): Class II (See 21 CFR 870.5300)

Automatic External Defibrillators have been considered Class III devices by FDA.

Substantial Equivalence:

This defibrillator is substantially equivalent to the currently marketed Physio-Control LIFEPAK 500 automated external defibrillator, 510(k) nos. K983393 (Biphasic, cleared 6/6/99) and K955854 (Monophasic, cleared 11/4/96).

Description and Reason for 510(k):

The LIFEPAK 500 Automated External Defibrillator (AED) is a portable battery powered, low energy defibrillator that applies a pulse of electricity to the heart via disposable defibrillation electrodes on the chest. A patented software algorithm analyzes the patient's electrocardiogram (ECG) and informs the operator if it detects a shockable rhythm. The operator can then press the shock button to deliver energy.

With the LIFEPAK 500 AED, shocks are not limited to a single energy setting; the device can be programmed to deliver subsequent shocks at higher energies if the first one is not successful.

The subject of this 510(k) is a change to the operating instructions and voice prompts related to pulse checks by lay users. There will be two levels of voice prompts that can be selected in the setup mode: the original voice prompt, "check for pulse – if no pulse start CPR" or the new prompt "check patient - if not moving and not breathing normally, start CPR.

Operating instructions now advise the user to "check for signs of circulation, e.g., no pulse, no coughing, no movement."

Intended Use:

The LIFEPAK 500 AED may be used in the hospital or pre-hospital setting by emergency responders to terminate certain potentially fatal cardiac arrhythmias. It is not intended for use on pediatric patients less than eight years of age.

Technological characteristics of new and predicate devices:

The features and functions of the new LIFEPAK 500 AED are the same as those of the currently marketed LIFEPAK 500 AED.

Summary of Design Controls:

The 510(k) includes a summary of design control activities and a declaration of conformity to design controls.

Conclusion:

The LIFEPAK 500 AED has identical technological characteristics as the predicate version. The shock advisory algorithm, defibrillation waveforms, etc. are all the same. The intended user and intended patient populations are the same. The changes made are pursuant to recent recommendations in the American Heart Association Guidelines 2000 for CPR and ECC. The rationale for those recommendations are presented in detail in that document and summarized in this 510(k). Because this is a Special 510(k), a summary of design control activities and a declaration of conformity to design controls are included.

The information in this 510(k) notification demonstrates that the modified LIFEPAK 500 AED is substantially equivalent to the predicate devices with respect to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2001

Ms. Sherri L. Pocock
Medtronic Physio-Control Corp.
11811 Willows Road NE
P.O. Box 97006
Redmond, WA 98073-9706

Re: K012428
LIFEPAK 500 Automated External Defibrillator
Regulation Number: 870.1025
Regulation Name: Arrythmia Detector and Alarm
Regulatory Class: III (three)
Product Code: MKJ
Dated: September 5, 2001
Received: September 7, 2001

Dear Ms. Pocock:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D: STATEMENT OF INDICATIONS FOR USE

Ver/ 3 - 4/24/96

Applicant: Medtronic Physio-Control

510(k) Number (if known): Not yet assigned K012428

Device Name: LIFEPAK 500 Automated External Defibrillator

Indications For Use:

The LIFEPAK 500 AED is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, not breathing normally and showing no signs of circulation (for example, no pulse, no coughing, no movement) before the device is used to analyze the patient's ECG rhythm. This device is not intended for use on children less than eight years of age, per AHA/ILCOR Guidelines.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012428

Prescription Use X
(Per 21 CFR 801.109)